

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/938,667	PETERSEN, JENS	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to supplemental response filed 2/27/06.
2.  The allowed claim(s) is/are 9-17, 29-32, 34-38, 47, 52-55, 57, 62, 63 and 67-69 (claims are renumbered).
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
 of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 4/8/04, 12/14/05, 2/13/2006; 2/27/06.
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date 4/25/06.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

Examiner acknowledges receipt of IDS filed 4/08/04, 12/14/2005 and 2/13/2006, amendment and remarks filed 12/14/05 and supplemental amendment and remarks filed 2/27/06. Claims 9-17, 29-32, 34-38, 47, 52-55, 57, 62, 63, 67-69 and new claims 71-77 are pending.

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 9-17, 29-32, 34-38, 47, 52-55, 57, 62, 63, 67-69, drawn to method of treating urinary incontinence, classified in class 424, subclass 78.31
  - II. Claims 71-77, drawn to method of treating anal incontinence, classified in class 424, subclass 78.31.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions method of treating anal incontinence and method of treating urinary incontinence. Due to the different physiological aspects of treating these two different types of incontinence, they would be considered different methods of treatment in the art. Clearly, the two methods could have very different means of treatment.
3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
4. During a telephone interview with applicants' attorneys Victoria Silcott and Stanislous Aksman on 4/25/06, applicants elected Group I with traverse to prosecute the invention of Group

II, claims 71-77 in a divisional application. Applicants' representatives authorized the cancellation of claims 71-76 and amendment of relevant claims to correct claim dependencies.

#### **EXAMINER'S AMENDMENT**

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with attorneys Victoria Silcott and Stanislaus Aksman on 4/26/06.

The application has been amended as follows:

Amend the following claims as follows:

Claim 10. (Currently amended) The method according to claim 9[,] or 54, [ or 71 or 72]wherein the polymer is prepared by combining acrylamide and [methylene-bis-acrylamide] methylene bis-acrylamide in a molar ratio of 1 50:1 to 1000:1.

Claim 11. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the hydrogel comprises less than 15% by weight of the polymer, based on the total weight of the hydrogel.

Claim 12. (Currently amended) The method according to claim [11] 9[,] or 54, [or 71,]wherein the hydrogel comprises at least 1% by weight of the polymer, based on the total weight of the hydrogel.

Claim 13. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the hydrogel has a complex viscosity of about 2 to 40 Pas.

Claim 14. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the hydrogel comprises at least 80% by weight water or aqueous solution.

Claim 29. (Currently amended) The method according to claim 9[.] or 54, [or 71,]wherein the hydrogel comprises less than 10% by weight of the polymer, based on the total weight of the hydrogel.

Claim 30. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the hydrogel comprises less than 7.5% by weight of the polymer, based on the total weight of the hydrogel.

Claim 31. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the hydrogel comprises less than 5% by weight of the polymer, based on the total weight of the hydrogel.

Claim 32. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the hydrogel comprises less than 3.5% by weight of the polymer, based on the total weight of the hydrogel.

Claim 34. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the hydrogel comprises at least 1 .6% by weight of the polymer, based on the total weight of the hydrogel.

Claim 35. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the hydrogel has a complex viscosity of about 2 to 30 Pas.

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Claim 36. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the hydrogel has a complex viscosity of about 2 to 20 Pas.

Claims 47. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the hydrogel has a complex viscosity of about 2 to 50 Pas.

Claim 52. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the polymer is substantially comprised of cross-linked polyacrylamide.

Claim 53. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the polymer consists essentially of a [polymer prepared by polymerizing acrylamide in the presence of a cross-linking agent]polyacrylamide cross-linked with methylene bis-acrylamide.

Claim 54. (Currently amended) A method of treating urinary incontinence comprising directly injecting a hydrogel into at least one of the conduits selected from the group consisting of [the] a urethra and a neck of a bladder, [rectum, colon,]wherein the hydrogel comprises water or aqueous solution and about 0.5 to 25% by weight polymer having fewer than 50 ppm monomer units and [has]having a complex viscosity of about 2 to 90 Pas and an elasticity modulus of about 1 to 200 Pas, the polymer prepared by combining acrylamide and a cross-linking agent methylene bis-acrylamide.

Claim 55. (Currently amended) The method of claim 54 [or 72 ]wherein the aqueous solution is a saline solution [and the cross-linking agent is methylene bis-acrylamide].

Claim 62. (Currently amended) The method according to claim 9[.] or 54, [or 71,]wherein the hydrogel comprises at least 75% by weight water or aqueous solution.

Claim 67. (Currently amended) The method according to claim 9[,] or 54, [or 71,] wherein the hydrogel has an elasticity modulus of about 5 to 150 Pas.

Claim 68. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the hydrogel has an elasticity modulus of about 10 to 100 Pas.

Claim 69. (Currently amended) The method according to claim 9[,] or 54, [or 71,]wherein the elasticity modulus and the complex viscosity are related by a factor of 5.8 to 6.4.

Claims 71-77 have been cancelled.

*Allowable Subject Matter*

6. The following is an examiner's statement of reasons for allowance: The primary reasons for allowance is administering the composition having specific viscosities and modulus of elasticity as claimed into the urethra or neck of the bladder as opposed to the ureter in the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara". The signature is fluid and cursive, with "B" and "F" being prominent.